

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 02-10258-RWZ

PALOMAR MEDICAL TECHNOLOGIES, INC. and
THE GENERAL HOSPITAL CORPORATION

v.

CUTERA, INC.

MEMORANDUM OF DECISION AND ORDER

December 12, 2005

ZOBEL, D.J.

Plaintiffs Palomar Medical Technologies, Inc. and the General Hospital Corporation are the owners of United States Patent No. 5,735,844 (“the ’844 patent”), “Hair Removal Using Optical Pulses.” They allege that defendant Cutera, Inc., formerly known as Altus Medical, Inc., produces and sells laser hair removal devices — known as “CoolGlide” — that infringe claims 12, 27, and 32 of the ’844 patent. Following a Markman hearing, the Court issued an order construing certain disputed terms. (See Feb. 24, 2004 Order). Cutera now moves for summary judgment on all three asserted claims, on grounds of invalidity and non-infringement.

I. Invalidity

Cutera first argues that asserted claims 12, 27, and 32 are invalid because they were anticipated by prior art. Because patents are presumed valid, see 35 U.S.C. § 282, Cutera must prove invalidity by clear and convincing evidence, see Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1480 (Fed. Cir. 1997). Summary judgment on

grounds of anticipation, which is a question of fact, is appropriate only if there is no dispute as to any material fact, or if there is no reasonable basis upon which the non-movant may prevail, even if all inferences are drawn in its favor. See Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). An asserted claim is invalid due to anticipation only if all elements and limitations of the claim are found within a single prior art reference. Id. There can be no difference between the claimed invention and the reference disclosure, as viewed by “a person of ordinary skill in the field of the invention.” Id.

Cutera asserts that claims 27 and 32 were anticipated by a 1967 journal article in Laboratory Investigation, by James G. Kuhns and others (“Kuhns reference”). Both claims contain as an element “[a] method for the simultaneous removal of a plurality of hairs from a skin region,” which, under the Court’s claim construction, means a method for removing more than one hair at the same time from an area of skin. (Feb. 24, 2004 Order, at 2). Cutera contends that this element is disclosed by Figure 7 of the Kuhns reference, as well as its accompanying text and legend. The Court disagrees. Figure 7 shows two hair follicles within a “[l]esion in moderately pigmented pig skin” caused by laser radiation. (Garretson Decl., Ex. 5, at WG 5280). Specifically, the image shows an “[a]blated epidermis, intact superficial dermis, and hair follicles, with alteration from heat on the side toward the beam.” (Id.). In other words, the Kuhns reference instructs that hair follicles may be injured when the skin is sufficiently damaged by laser radiation to result in ablation, or severe burning, of the epidermis. Hair removal associated with severely burnt skin does not disclose removal of hair from a skin

region, but rather removal of hair as well as skin. Were the Court to find that damage to hair follicles accompanied by severe burning of the skin, as disclosed in Kuhns, constituted “removal of hairs . . . from a skin region,” then, as plaintiffs’ expert Dr. Bass points out, “even a blowtorch would be considered to be an apparatus for simultaneous removal of hair from skin.” (Saxton Decl., Ex. 5, ¶ 17). The Kuhns reference therefore did not anticipate claims 27 or 32, since it failed to disclose at least one element of those claims. See Scripps Clinic & Research Found., 927 F.2d at 1576 (anticipation requires that all elements and limitations be found in single prior art reference).

Cutera next contends that claims 12 and 27 were anticipated by a 1983 article authored by T. Ohshiro and Y. Maruyama (“Ohshiro reference”). This argument fails for similar reasons. Claim 12, like claims 27 and 32, describes the “simultaneous removal of a plurality of hairs from a skin region.” The Ohshiro reference teaches hair removal to the extent that it discloses the removal of naevi, or skin lesions. (Garretson Decl., Ex. M, at PAL019977). The Ohshiro reference teaches that naevi, including hairy naevi, are removed by laser radiation that (1) damages the epithelium, (2) destroys the dermo-epidermal junction (i.e., the layer between the dermis and the epidermis), and (3) allows the treating physician to “easily peel[]” away the epithelium. (Id. at PAL019978). In other words, the Ohshiro reference instructs removal of hairy naevi by first damaging and then entirely removing a layer of skin. As explained above, a prior art reference that instructs removal of hair by destroying the surrounding skin does not anticipate claims 12 or 27, which teach the removal of hair from skin.

Because neither Kuhns nor Ohshiro teaches the simultaneous removal of a plurality of hairs from a skin region, they do not anticipate the asserted claims.

Cutera's motion for summary judgment on grounds of invalidity is therefore denied.

II. Infringement

Cutera also seeks summary judgment on the basis of non-infringement.

Plaintiffs have alleged both direct infringement and inducement of infringement. A patentee claiming direct infringement must "show that the accused device contains or performs each limitation of the asserted claims," either literally, or under the doctrine of equivalents. TI Group Auto. Sys. Inc. v. VDO N. Am., LLC, 375 F.3d 1126, 1139-40 (Fed. Cir. 2004). To show inducement of infringement, plaintiffs must show that Cutera committed acts causing another to infringe and that it "knew or should have known [its] actions would induce actual infringements." Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990). Defendants who seek a finding of non-infringement at the summary judgment stage face an uphill battle, since infringement is a question of fact, and, particularly under the doctrine of equivalents, may require "difficult factual determinations." Leggett & Platt, Inc. v. Hickory Springs Mfg. Co., 285 F.3d 1353, 1360 (Fed. Cir. 2002). The Court may grant Cutera's summary judgment motion only if there is no dispute as to any material factual issue. See Techsearch, LLC v. Intel Corp., 286 F.3d 1360, 1370-71 (Fed. Cir. 2002).

A. Claim 12

Claim 12 of the '844 patent states:

12. A method for the simultaneous removal of a plurality of hairs from a skin region . . . , the method comprising the steps of:
 (a) placing an applicator in contact with the skin surface in said skin region; and
 (b) applying optical radiation of a selected wavelength and of a selected fluence through said applicator to said skin region . . . ;
pressure being applied to the applicator during steps (a) and (b) so as to cause the applicator to deform the skin region thereunder.

In this Court's claim construction order, the term "applicator" was construed as meaning "[a] device for applying optical radiation," and the phrase "pressure being applied to the applicator . . . so as to cause the applicator to deform the skin region thereunder" was construed as meaning "pressure being applied to the applicator so as to cause the applicator to compress the area of skin under it." (Feb. 24, 2004 Order, at 3).

Cutera seemingly concedes that the CoolGlide handpieces are "applicators" within the meaning of claim 12, but denies that pressure is applied to the handpieces. Cutera's first argument is that pressure is not applied to the CoolGlide handpieces because doing so would make little sense. Cutera points out that the '844 patent calls for pressure to be applied to the applicator in order to achieve a specific purpose, i.e., "more efficient delivery of light to the follicular target regions" (Garretson Decl., Ex. A, at 6:60-66). Because applying pressure to Cutera's devices allegedly would not achieve this result, Cutera maintains that pressure is not applied to the accused devices within the meaning of claim 12.

However, claim 12 does not refer to the reasons for applying pressure to the applicator; it merely describes the application of pressure as part of the patented method. The Court's Markman order construed claim 12 simply as specifying that a

certain amount of pressure (i.e., an amount sufficient to compress the underlying skin) be applied to the applicator. (See Feb. 24, 2004 Order, at 3). The issue before the Court, therefore, is not why pressure is applied to the accused devices (or why not), but rather whether or not pressure sufficient to compress the underlying skin is applied to the accused devices. On this issue, summary judgment is inappropriate. According to Cutera, no “appreciable” compression of the skin occurs during use of the accused products, and any compression of the skin is “minimal.” (Cutera Jan. 14, 2005 Mem., at 13 n.6). The chilled footplate is, Cutera maintains, never pressed into the skin, but is instead “glided over the skin.” (Id. at 12). Whether compression of the underlying skin occurs during use of the Cutera devices, however, and whether that pressure results in compression that is “appreciable” or more than “minimal” are disputed questions of fact. As Palomar notes, Cutera’s training and instruction materials warn users to ensure that the footplate remains in contact with the skin, “especially over curves.” (Saxton Decl., Ex. 15, at ALT 000137). Reasonable jurors could find that pressure sufficient to compress the underlying skin was required in order to maintain constant contact between the footplate and curved areas of skin. Furthermore, a video displayed at oral argument on Cutera’s motion depicts through animation the application of a Cutera product; the animation shows the skin beneath the Cutera device being somewhat compressed as the footplate passes over the skin. Perhaps most significant, the record includes the notes of Michael Sasnett, the designer of a prototype of the CoolGlide products, which state that the handpiece is to be pressed upon the skin. (Saxton Decl., Ex. 22, at ALT 017390).

Cutera argues that even if the skin beneath the applicator is somehow compressed, there is no evidence in the record that such compression results from pressure being brought to bear upon the applicator, and further challenges the relevance of Sasnett's notes, which it claims reflect only early stages of product development. On a motion for summary judgment, however, the Court draws inferences in the nonmovant's favor; in doing so, it is clear that a material issue of fact exists as to whether pressure sufficient to compress the underlying skin is applied to Cutera's CoolGlide devices. For substantially the same reasons, a factual dispute exists as to whether Cutera intends that its customers apply pressure to its devices so as to compress the skin under them and thereby induces infringement. Accordingly, summary judgment as to both direct infringement and inducement of infringement of claim 12 is denied.

B. Claim 27

Claim 27 of the '844 patent covers an "[a]pparatus for the simultaneous removal of a plurality of hairs from a skin region," consisting of:

An applicator which is adapted to be in pressure contact with a portion of the skin surface containing a plurality of hairs in said skin region;
a source of optical radiation . . .; and
means for applying the optical radiation from said source to said applicator, the optical radiation being passed through the applicator to said skin region.

Cutera argues that claim 27 requires that the applicator be in pressure contact with and irradiate the same area of skin at the same time. (See, e.g., Cutera Jan. 14, 2005 Mem., at 16 (characterizing claim 27 as describing "an area of skin that is being simultaneously contacted and irradiated")). The footplate of the Cutera handpiece is,

by contrast, placed in contact with an area of skin to pre-cool that area; the handpiece is then moved so that the pre-cooled area is no longer touching the applicator, but is instead directly below a laser beam, which is projected from a recessed area of the applicator. The pre-cooled area is therefore not touching the handpiece while it is irradiated by this beam; instead, an adjacent area of skin is placed in contact with the footplate of the applicator and pre-cooled. Because the area of skin being irradiated is not in contact with the handpiece at the same time that it is being irradiated, and because the irradiation is not applied to the skin through the surface that touches the skin, Cutera maintains that its devices do not literally infringe claim 27.

Again, Cutera is attempting to read a limitation into claim 27 that does not exist. During the claim construction phase, Cutera asserted the same position, contending that claim 27 required that optical radiation be applied to the skin “through the surface of the applicator in contact with the skin surface.” (Cutera May 23, 2003 Mem., at 15-16). The Court rejected that argument at the time and continues to do so. Claim 27 requires (1) that the applicator be placed in pressure contact with the targeted skin region; (2) that optical radiation be passed through the applicator; and (3) that the optical radiation passed through the applicator be applied to the targeted skin region. It does not, however, purport to require that all three of those elements occur simultaneously, nor, under the Court’s claim construction order, does claim 27 require that optical radiation pass through the portion of the applicator whose surface is in contact with the patient’s skin. Cutera does not deny that the CoolGlide handpieces are placed in contact with the targeted area of skin or that optical radiation is passed

through the applicator to that same targeted area of skin; it simply argues that those two functions do not occur simultaneously and that the optical radiation does not pass through that portion of the applicator that touches the skin. Cutera cannot prevail on summary judgment simply by reading its own limitations into claim 27 and then arguing that its devices are not encompassed by those limitations.

Moreover, even were the Court to accept for purposes of argument Cutera's assertion that claim 27 requires that the area of skin touching the applicator must simultaneously be irradiated, evidence in the record raises a triable issue of fact as to that limitation. The illustration of the accused devices in Cutera's own submissions indicate that the portion of the applicator touching the patient's skin includes not only the footplate, but also two treatment guides, that extend beyond the footplate and partially surround the area currently being irradiated. (See Cutera Jan. 14, 2005 Mem., at 16). According to plaintiffs' expert, Dr. Bass, scattering of laser radiation within the skin tissue may result in irradiation of follicles below the treatment guides. (Saxton Decl., Ex. 2 ¶ 93). In other words, areas of skin that are in contact with the treatment guides may be irradiated at the same time that they are touching the treatment guides. Accordingly, summary judgment as to claim 27 is denied.

C. Claim 32

Claim 32, a method claim, requires "positioning an element" over the area of skin to be irradiated. Cutera's non-infringement argument with respect to claim 32 is based on the Court's construction of the term "element" as "a device or component of a device for converging optical radiation." (Feb. 24, 2004 Order, at 4). Cutera begins by

referring to the definition of “converge” contained in the American Heritage Dictionary, as moving “toward a common point,” and then argues that light exiting the lens in its accused devices is actually diverging, rather than moving toward a common point.

It is undisputed that the accused devices contain at least one convex lens through which laser radiation passes before reaching the targeted skin region. While Cutera points to deposition testimony of Kevin Connors, its president and CEO, in which he states that the “light leaving the lens is diverging,” (Garretson Decl., Ex. X, at 101:23-24), there seems to be no dispute that the lens is convex, since both Mr. Connors and Cutera’s expert witness Dr. Clement agreed that the accused devices contain a lens that is thicker in the middle than at the edges. (*Id.* at 107:7-9; Saxton Supp. Decl., Ex. I, at 201-03). Plaintiffs argue that a convex lens is, by definition, a lens that converges optical radiation, citing the Academic Press Dictionary of Science and Technology, which defines a “converging lens” is one where the “lens is thicker at its center than at its edge.” (Saxton Supp. Decl., Ex. K, at 517). Given these dueling definitions of “converging,” and drawing all inferences in favor of the nonmovants, a triable issue of fact exists as to whether the convex lens contained in Cutera’s CoolGlide devices does tend to move the optical radiation toward one point.

D. Claims 12, 27, and 32

Finally, Cutera raises a separate non-infringement argument as to all three of the asserted claims. Cutera contends that if the Court accepts for invalidity purposes plaintiffs’ construction of “simultaneous removal of a plurality of hairs from a skin region” to mean removal of hair with little or no damage to the surrounding skin, it must

apply the same construction to judge infringement. Further, says Cutera, Palomar has failed to present any evidence that Cutera's devices remove hair without damaging surrounding skin, and has therefore failed to raise a material issue of fact as to a limitation of the asserted claims. The record does, however, contain evidence indicating that Cutera's products remove hair while minimizing or eliminating damage to surrounding tissue and that Cutera deliberately markets this feature of its CoolGlide products. The CoolGlide Treatment Guidelines, for example, repeatedly refer to steps to be taken by practitioners to avoid "unwanted epidermal damage," to "provide the greatest epidermal safety," and to "provide increased epidermal protection." (Saxton Decl., Ex. 15). Practitioners using Cutera's CoolGlide devices are further instructed to monitor the epidermis during treatment for "signs of damage (epidermal separation or gray coloration," and, if damage is observed, to "reduce the fluence." (Id.). The website of one of Cutera's customers describes the CoolGlide as achieving laser hair removal "without causing unwanted thermal damage to surrounding tissue," and further notes that the CoolGlide product cools the epidermis "to prevent epidermal damage." (Saxton Decl., Ex. 19). Summary judgment on that basis is therefore denied.

III. Conclusion

Accordingly, Cutera's motion for summary judgment on grounds of invalidity and non-infringement (#142 on the Docket) is denied.

DATE

/s/ Rya W. Zobel

RYA W. ZOBEL

UNITED STATES DISTRICT JUDGE